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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/160,965	12/02/1993	JAMES M. MUSSER	06239007001	2506

26271 7590 06/19/2003  
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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 06/19/2003

60

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application N .

08/160,965

Applicant(s)

MUSSEY ET AL.

Examiner

Ja-Na Hines

Art Unit

1645

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 1,4-35,46 and 47.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of claims 1, 4-35 and 45-47 under 35 U.S.C. 112, second paragraph.

Continuation of 5. does NOT place the application in condition for allowance because: The written description rejection of claims 1, 4-35, 44 and 46-47 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

The amended claims are now drawn to an immunogenic composition and method of producing an immune response comprising a cysteine protease comprising at least one amino acid substitution and said substitution occurs at specific positions, however, the claims and specification appear to fail to recite the reference sequence from which the amino acid substitutions are drawn.

Applicants assert that at least 33 of the 39 identified alleles differ in sequence but that sequences for SpeB were known at the time of applicants invention. However the claims still fail to recite the base sequence that is being mutated. Without knowing the reference sequence, one cannot really know the significance of substituting lys145 or the like.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of using but rather the reference sequence is required in order that one in the art known exactly which amino acids are being mutated. Thus a precise description of the reference sequence is necessary. Thus the specification is insufficient to support the instant claims.

In view of these considerations, a person skilled in the art would not have viewed the teachings of the specification sufficient to show that applicants were in possession of an immunogenic composition comprising the mutated cysteine protease and method of producing an immune response as asserted in the specification as instantly claimed.

  
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